

A/644

**TRANSMITTAL  
FORM**



<b>TRANSMITTAL FORM</b>	Application Serial Number	10/037,296
	Filing Date	December 21, 2001
	First Named Inventor	Dahlbäck
	Group Art Unit	1644
	Examiner Name	Saunders, David A.
	Attorney Docket No.	INL-054DV
	Patent No.	Not applicable
	Issue Date	Not applicable

**ENCLOSURES (check all that apply)**

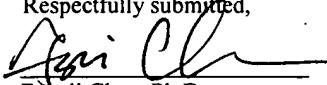
<input checked="" type="checkbox"/> Fee Transmittal Form  <input checked="" type="checkbox"/> Check Attached <input type="checkbox"/> Copy of Fee Transmittal Form	<input type="checkbox"/> Copy of Notice to File Missing Parts of Application	<input type="checkbox"/> Notice of Appeal to Board of Patent Appeals and Interferences	
	<input type="checkbox"/> Formal Drawing(s)	<input type="checkbox"/> Appeal Brief (in triplicate)	
	<input type="checkbox"/> Amendment/Response	<input type="checkbox"/> Request For Continued Examination (RCE) Transmittal	<input type="checkbox"/> Status Inquiry
	<input type="checkbox"/> Preliminary <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Letter to Official Draftsperson including Drawings [Total Sheets ___]	<input type="checkbox"/> Power of Attorney (Revocation of Prior Powers)	<input checked="" type="checkbox"/> Return Receipt Postcard
		<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Certificate of First Class Mailing under 37 C.F.R. 1.8
	<input type="checkbox"/> Petition for Extension of Time	<input type="checkbox"/> Executed Declaration and Power of Attorney for Utility or Design Patent Application	<input type="checkbox"/> Certificate of Facsimile Transmission under 37 C.F.R. 1.8
	<input checked="" type="checkbox"/> Information Disclosure Statement <input checked="" type="checkbox"/> Form PTO-1449 <input checked="" type="checkbox"/> Copies of IDS Citations (B17-B19 and C157-C170)	<input type="checkbox"/> Small Entity Statement	<input type="checkbox"/> Additional Enclosure(s) (please identify below)
	<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD(s) for large table or computer program	
<input type="checkbox"/> Sequence Listing submission <input type="checkbox"/> Paper Copy/CD <input type="checkbox"/> Computer Readable Copy <input type="checkbox"/> Statement verifying identity of above	<input type="checkbox"/> Amendment After Allowance		
	<input type="checkbox"/> Request for Certificate of Correction <input type="checkbox"/> Certificate of Correction (in duplicate)		

**CORRESPONDENCE ADDRESS**

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 Graham LLP  
 75 State Street  
 Boston, MA 02109-1808  
 Tel. No.: (617) 261-3100  
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**SIGNATURE BLOCK**

Date: May 4, 2005  
 Reg. No. 51,551  
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 Fax No.: (617) 261-3175

Respectfully submitted,  
  
 Fangli Chen, Ph.D.  
 Agent for Applicant  
 Kirkpatrick & Lockhart Nicholson  
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 75 State Street  
 Boston, MA 02109-1808

<i>Complete if Known</i>	
Application Serial Number	10/037,296
Filing Date	December 21, 2001
First Named Inventor	Dahlbäck
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METHOD OF PAYMENT		FEE CALCULATION (continued)																																																																																															
1. <input checked="" type="checkbox"/> Payment Enclosed: <input checked="" type="checkbox"/> Check <input type="checkbox"/> Money Order <input type="checkbox"/> Other		<b>3. ADDITIONAL FEES</b> <table border="1"> <thead> <tr> <th>Large Entity Fee (\$)</th> <th>Small Entity Fee (\$)</th> <th>Fee Description</th> <th>Fee Paid</th> </tr> </thead> <tbody> <tr><td>130</td><td>65</td><td>Surcharge - late filing fee or oath</td><td></td></tr> <tr><td>50</td><td>25</td><td>Surcharge - late provisional filing fee or cover sheet</td><td></td></tr> <tr><td>130</td><td>130</td><td>Non-English specification</td><td></td></tr> <tr><td>2,520</td><td>2,520</td><td>Request for ex parte reexamination</td><td></td></tr> <tr><td>120</td><td>60</td><td>Extension for reply within first month</td><td></td></tr> <tr><td>450</td><td>225</td><td>Extension for reply within second month</td><td></td></tr> <tr><td>1020</td><td>510</td><td>Extension for reply within third month</td><td></td></tr> <tr><td>1590</td><td>795</td><td>Extension for reply within fourth month</td><td></td></tr> <tr><td>2160</td><td>1080</td><td>Extension for reply within fifth month</td><td></td></tr> <tr><td>500</td><td>250</td><td>Notice of Appeal</td><td></td></tr> <tr><td>500</td><td>250</td><td>Filing a brief in support of an appeal</td><td></td></tr> <tr><td>1000</td><td>500</td><td>Request for oral hearing</td><td></td></tr> <tr><td>400</td><td>400</td><td>Petitions to the Commissioner (Gp. I)</td><td></td></tr> <tr><td>200</td><td>200</td><td>Petitions to the Commissioner (Gp. II)</td><td></td></tr> <tr><td>130</td><td>130</td><td>Petitions to the Commissioner (Gp. III)</td><td></td></tr> <tr><td>180</td><td>180</td><td>Submission of Supplemental Information Disclosure Statement</td><td>\$180.00</td></tr> <tr><td>790</td><td>395</td><td>Filing a submission after final rejection (37 CFR 1.129(a))</td><td></td></tr> <tr><td>790</td><td>395</td><td>For each additional invention to be examined (37 CFR 1.129(b))</td><td></td></tr> <tr><td>100</td><td>100</td><td>Certificate of Correction for applicant's error</td><td></td></tr> <tr><td>130</td><td>65</td><td>Submission of Terminal Disclaimer</td><td></td></tr> <tr><td colspan="4">Other fee (Specify)</td></tr> <tr><td colspan="4">Other fee (Specify)</td></tr> </tbody> </table>				Large Entity Fee (\$)	Small Entity Fee (\$)	Fee Description	Fee Paid	130	65	Surcharge - late filing fee or oath		50	25	Surcharge - late provisional filing fee or cover sheet		130	130	Non-English specification		2,520	2,520	Request for ex parte reexamination		120	60	Extension for reply within first month		450	225	Extension for reply within second month		1020	510	Extension for reply within third month		1590	795	Extension for reply within fourth month		2160	1080	Extension for reply within fifth month		500	250	Notice of Appeal		500	250	Filing a brief in support of an appeal		1000	500	Request for oral hearing		400	400	Petitions to the Commissioner (Gp. I)		200	200	Petitions to the Commissioner (Gp. II)		130	130	Petitions to the Commissioner (Gp. III)		180	180	Submission of Supplemental Information Disclosure Statement	\$180.00	790	395	Filing a submission after final rejection (37 CFR 1.129(a))		790	395	For each additional invention to be examined (37 CFR 1.129(b))		100	100	Certificate of Correction for applicant's error		130	65	Submission of Terminal Disclaimer		Other fee (Specify)				Other fee (Specify)			
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2. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to credit or charge any fee indicated below for this submission to Deposit Account No. 50-1721. <input type="checkbox"/> Required Fees (copy of this sheet enclosed). <input checked="" type="checkbox"/> Additional fee required under 37 CFR 1.16 and 1.17. <input checked="" type="checkbox"/> Overpayment Credit.																																																																																																	
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CORRESPONDENCE ADDRESS			SIGNATURE BLOCK																																																																																														
Direct all correspondence to:			Respectfully submitted,  Fangli Chen, Ph.D. Attorney for the Applicants Kirkpatrick & Lockhart Nicholson Graham LLP 75 State Street Boston, MA 02109-1808 Tel. No.: (617) 261-3100 Fax No.: (617) 261-3175																																																																																														



PATENT  
Attorney Docket No. INL-054DV

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANT(S): Dahlbäck  
SERIAL NO.: 10/037,296 GROUP NO.: 1644  
FILING DATE: December 21, 2001 EXAMINER: Saunders, David A.  
TITLE: Methods and Reagents for Determining Protein S

**CERTIFICATE OF FIRST CLASS MAILING UNDER 37 C.F.R. 1.8**

I hereby certify that this correspondence, and any document(s) referred to as enclosed herein, is/are being deposited with the United States Postal Service as first class mail, postage prepaid, in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 4<sup>th</sup> day of May, 2005.

  
Kelly B. Giarmataro

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith is/are:

1. Transmittal Form (1 pg.);
2. Fee Transmittal (1 pg.);
3. Supplemental Information Disclosure Statement (2 pgs.);
4. PTO Form 1449 (2 pgs.) (including cited references B17-B19 and C157-C170);
5. a Check in the amount of \$180.00; and
6. Return Receipt Postcard.



PATENT  
Attorney Docket No. INL-054DV

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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SERIAL NO.: 10/037,296 GROUP NO.: 1644

FILING DATE: December 21, 2001 EXAMINER: Saunders, David A.

TITLE: Methods and Reagents for Determining Protein S

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

### SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the non-U.S. patent documents and non-patent publications are enclosed.

### REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- (2) after the period defined in (1) above but before the mailing date of any of a **final action** under 37 C.F.R. 1.113, a **notice of allowance** under 37 C.F.R. 1.311, or an action that otherwise closes prosecution in the application, and
  - the requisite Statement is below, **OR**
  - the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein; or

Supplemental Information Disclosure Statement

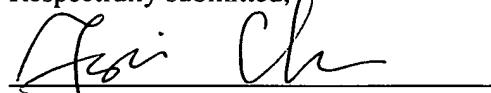
Serial No. 10/037,296

Page 2 of 2

- (3) after the period defined in (2) above but before the payment of the issue fee, AND
- the requisite Statement is below, AND
- the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the foreign patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

Respectfully submitted,



Fangli Chen, Ph.D.

Agent for Applicant(s)

Kirkpatrick & Lockhart Nicholson

Graham LLP

75 State Street

Boston, Massachusetts 02109-1808

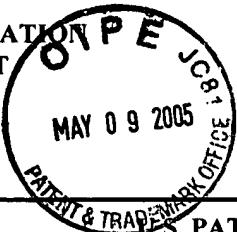
Date: May 4, 2005

Reg. No. 51,551

Tel. No.: (617) 261-3198

Fax No.: (617) 261-3175

BOS-841279 v1

<b>FORM PTO - 1449</b> <b>SUPPLEMENTAL INFORMATION</b> <b>DISCLOSURE STATEMENT</b>				<b>ATTORNEY DOCKET NO.:</b> INL-054DV <b>APPLICANT(S):</b> Dahlbäck <b>SERIAL NO.:</b> 10/037,296 <b>FILING DATE:</b> December 21, 2001 <b>GROUP NO.:</b> 1644					
 <b>U.S. PATENT DOCUMENTS</b>									
<b>EXAM. INIT.</b>		<b>DOCUMENT NUMBER</b>	<b>DATE</b>	<b>NAME</b>		<b>CLASS</b>	<b>SUB CLASS</b>	<b>FILING DATE IF APPROPRIATE</b>	
	A45	4,184,849	1/22/80	Cambiaso et al.					
	A46	4,210,723	7/1/80	Dorman et al.					
	A47	4,401,765	8/30/83	Craig et al.					
	A48	4,480,042	10/30/84	Craig et al.					
	A49	4,843,021	6/27/89	Noguchi et al.					
	A50	5,095,097	3/10/92	Hermentin et al.					
	A51	5,585,278	12/17/96	Vunnam et al.					
	A52	5,741,658	4/21/98	Morrissey et al.					
	A53	5,858,648	1/12/99	Steel et al.					
	A54	6,124,430	9/26/00	Mischak et al.					
<b>FOREIGN PATENT DOCUMENTS</b>									
<b>EXAM. INIT.</b>		<b>DOCUMENT NUMBER</b>	<b>DATE</b>	<b>COUNTRY CODE</b>	<b>CLASS</b>	<b>SUB CLASS</b>	<b>FILING DATE</b>	<b>ABSTRACT ONLY</b>	<b>ENGLISH LANG (Y/N)</b>
	B17	0476545 A1	03/25/92	EP				Y	Y
	B18	0944837 B1	12/01/04	EP				N	Y
	B19	98/23963	06/04/98	WO				N	Y
<b>OTHER ART, JOURNAL ARTICLES, ETC.</b>									
<b>EXAM. INIT.</b>	<b>OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)</b>								
	C 157	Brinkley "A Brief Survey of Methods for Preparing Protein Conjugates with Dyes, Haptens, and Cross-linking Reagents," <u>Bioconjugate Chemistry</u> , Vol. 3, No. 1, January/February 1992.							
<b>EXAMINER</b>					<b>DATE CONSIDERED</b>				

FORM PTO - 1449

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: INL-054DV

APPLICANT(S): Dahlbäck

SERIAL NO.: 10/037,296

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## OTHER ART, JOURNAL ARTICLES, ETC.

	C 158	Dahlback, B. "Purification of Human Vitamin K-Dependent Protein S and its limited proteolysis by Thrombin" <u>The Biochemical Journal</u> , Vol. 209, No. 3, pp. 847-856, March 1, 1983.
	C 159	Dahlback, B. "Purification of Human C4b-binding Protein and Formation of its Complex with Vitamin K-dependent protein S" <u>The Biochemical Journal</u> , Vol. 209, No. 3, p. 837-846, March 1, 1983..
	C 160	Deffert et al., "A Direct, Automated, Immuno-Turbidimetric Assay of Free Protein S Antigen in Plasma" <u>Blood Coagulation and Fibrinolysis</u> , Vol. 12, No. 2, pp. 137-141, March 2001.
	C 161	Deutz-Terlouw et al., "Two ELISA's for measurement of protein S, and their use in the laboratory diagnosis of protein S deficiency", <u>Clinica Chimica Acta</u> , Bol 186, pp. 321-334, 1989.
	C 162	Erlanger, "Principles and Methods for the Preparation of Drug Protein Conjugates for Immunological Studies" <u>Pharmacological Reviews</u> , Vol. 25, No. 2: 271-280, 1973.
	C 163	Faioni et al. "Free Protein S Deficiency Is a Risk Factor for Venous Thrombosis" <u>Thrombosis and Haemostasis</u> , Vol. 78, No. 5, pp. 1343-1346, November 1997.
	C 164	Giri et al. "A New Direct, Fast and Quantitative Enzyme-linked Ligandsorbent Assay for Measurement of Free Protein S Antigen" <u>Thrombosis and Haemostasis</u> , Vol. 79, No. 4, pp. 767-772, April 1998.
	C 165	Murdock et al. "A Simple Monoclonal Antibody based ELISA for Free Protein S. Comparison with PEG Precipitation" <u>Clinical and Laboratory Haematology</u> , vol.19, pp. 111-114, 1997.
	C 166	Liles et al. "Prevalence of Factor V Leiden In Patients With Venous Thrombosis at a Major Referral Center for Thrombotic Conditions" <u>Thrombosis and Haemostasis</u> , Vol. 73, pg. 1259, June 6-12, 1997.
	C 167	Simmonds et al. "Genetic and Phenotypic Analysis of a Large (122-Member) Protein S- Deficient Kindred Provides an Explanation for the Familial Coexistence of Type I and Type III Plasma Phenotypes", <u>Blood</u> , Vol. 89, No. 12, pp. 4364-4370, June 15, 1997.
	C 168	Tombesi et al., "Evaluation of a New Method for Protein S Detection Using Monoclonal Antibodies", <u>Current Studies in Hematology and Blood Transfusion</u> , Vol. 58, pgs. 205-210, XP002123209, 1991.
	C 169	PCT Written Opinion of PCT/SE 97/01907, 6 pgs., January 1994.
	C 170	PCT International Search Report for PCT/US01/490006, 4 pgs. December 2002.

EXAMINER

DATE CONSIDERED